

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

21 FEB 2006

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Applicant's or agent's file reference SDS:BR:FP21285	<b>FOR FURTHER ACTION</b>	See Form PCT/IPEA/416
International application No. <b>PCT/AU2005/000442</b>	International filing date ( <i>day/month/year</i> ) 30 March 2005	Priority date ( <i>day/month/year</i> ) 30 March 2004
International Patent Classification (IPC) or national classification and IPC  Int. Cl.  <b>A61K 31/19 (2006.01)      A61P 29/02 (2006.01)</b>		
Applicant  <b>THE UNIVERSITY OF SYDNEY et al</b>		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a. ☐ (*sent to the applicant and to the International Bureau*) a total of      sheets, as follows:

☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☐ (*sent to the International Bureau only*) a total of (indicate type and number of electronic carrier(s))      , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input type="checkbox"/> Box No. II	Priority
<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input type="checkbox"/> Box No. VIII	Certain observations on the international application

Date of submission of the demand 30 January 2006	Date of completion of this report 10 February 2006
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  <b>TAMARA NIZNIK</b> Telephone No. (02) 6283 2422

**Box No. I**      **Basis of the report**1. With regard to the **language**, this report is based on:☒ The international application in the language in which it was filed☐ A translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of:☐ international search (under Rules 12.3(a) and 23.1 (b))☐ publication of the international application (under Rule 12.4(a))☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):☐ the international application as originally filed/furnished☐ the description:

pages as originally filed/furnished

pages\* received by this Authority on with the letter of

pages\* received by this Authority on with the letter of

☐ the claims:

pages as originally filed/furnished

pages\* as amended (together with any statement) under Article 19

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☐ the drawings:

pages as originally filed/furnished

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☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.3. ☐ The amendments have resulted in the cancellation of:☐ the description, pages☐ the claims, Nos.☐ the drawings, sheets/figs☐ the sequence listing (*specify*):☐ any table(s) related to the sequence listing (*specify*):4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).☐ the description, pages☐ the claims, Nos.☐ the drawings, sheets/figs☐ the sequence listing (*specify*):☐ any table(s) related to the sequence listing (*specify*):

\* If item 4 applies, some or all of those sheets may be marked "superseded."

**Box No. V** Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims 1-29	YES
	Claims	NO
Inventive step (IS)	Claims 1-29	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-29	YES
	Claims	NO

## 2. Citations and explanations (Rule 70.7)

- D1. WO 2004/000215 A2 (Medinox Inc) 31 December 2003
- D2. Roch-Arveiller M et al "Effects of some non-steroidal anti-inflammatory drug copper complexes on polymorphonuclear leukocyte oxidative metabolism" Agents and Actions (1990) Vol 31 (1-2) pages 65-71
- D3. Roch-Arveiller M et al "Non-steroidal anti-inflammatory drug-copper complex modulation of polymorphonuclear leukocyte migration" Biochemical Pharmacology (1990) Vol 39(3) pages 569-74
- D4. West GB "Testing for drugs inhibiting the formation of gastric ulcers" Journal of Pharmacological Methods (1982) Vol 8(1) pages 33-7

Novelty (N)

Claims 1-29 meet the criteria set forth in PCT Article 33(2) for novelty. D1 discloses a hydroxamate complex of NSAIDs in an emulsion, dispersion, or a micelle. D2 discloses metal complexes of NSAIDs. D3 discloses metal complexes of NSAIDs suspended in water soluble methyl cellulose. D4 discloses copper salicylate in water soluble Tween 80. The prior art published before the priority date therefore, does not independently disclose a composition comprising a metal complex of a carboxylate having anti-inflammatory activity, wherein the composition has a colloidal structure, or forms a colloidal structure, or is immiscible with water.

Inventive Step(IS)

The prior art published before the priority date, does not independently or when considered together teach or suggests a composition comprising a metal complex of a carboxylate having anti-inflammatory activity, wherein the composition has a colloidal structure, or forms a colloidal structure, or is immiscible with water and have more than 80% of the total amount of the carboxylate having anti-inflammatory activity in the composition is present as part of a metal complex, and less than 10% of the carboxylate having antiinflammatory activity complexed with the metal disassociates from the metal over twelve months when the composition is stored in the absence of light at room temperature. Therefore Claims 1-29 have an inventive step.

Industrial Applicability (IA)

The invention defined in claims 1-29 is industrially applicable.